

Application No.: 10/052,601

Docket No.: EGYPT 3.0-019

IN THE DRAWINGS

Please substitute the attached replacement pages 1-5 designated "REPLACEMENT PAGE 1/6," "REPLACEMENT PAGE 2/6," "REPLACEMENT PAGE 3/6," "REPLACEMENT PAGE 4/6" and "REPLACEMENT PAGE 5/6" in place of drawing pages 1/6 through 5/6.

Attachment: Replacement Sheets 1/6 through 5/6

REMARKS

Entry of the foregoing and reconsideration of the above-identified application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112 are respectfully requested. By this amendment, claims 1-4 and 8-25 are presented, claims 1, 13 and 19 are amended, claims 26-28 are added and claims 5, 6 and 7 are canceled.

Applicant notes the objections to Figures 1C, 2B, 3B, 4B and 5B. Applicant has provided herewith substitute pages with better figures for the Examiner's consideration. However, it is respectfully submitted that no such corrections were necessary. The objected to drawings are depictions of the actual gels from various electrophoresis testing, and the pictures adequately convey the necessary information to those of ordinary skill in the art. Moreover, the cited figures respectively reflect the gel as analyzed according to a densitometric profiles which corresponds to Figures 1D, 2C, 3C, 4C and 5C, and those of ordinary skill in the art would understand these figures in that context.

A provisional double patenting rejection was applied against claim 7, as it was allegedly duplicative of claim 6. However, applicant respectfully traverses this rejection. While claim 7 is indeed duplicative and has been canceled, it is not believed that it is appropriate to issue a double patenting rejection amongst claims within a single patent application. Perhaps there are other bases such as duplicity or multiplicity which could have been applied. In any event, the Examiner's observation that the claim substantially duplicates claim 6, indeed, necessitated cancellation of claim 7.

Claims 6 and 19 were rejected pursuant to 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. Applicant respectfully submits, however, that claim 6 has been canceled, and therefore, the rejection is moot. As

to claim 19, the Examiner's observation is correct, and the claim has been amended to delete C₁ and replaced with C₁₀. In addition, applicant has noted a spelling error in claim 13 and has corrected same.

Claims 1-5, 10-14, 16 and 22-25 have been rejected pursuant to 35 U.S.C. § 102(b) as allegedly being anticipated by *Grushka et al.*, U.S. Patent 5,660,701. As the rejection would be applied to claim 1 as amended, applicant respectfully traverses. *Grushka et al.* does not teach the biological buffers of claim 6 which have been incorporated into claim 1. Indeed, they teach the use of amino acids as buffers, and suggest that preferably no other buffering agents other than amino acids be used. (See col. 3, lns. 32-47; col. 4, lns. 20-21.) Because *Grushka et al.* does not disclose each and every element of claim 1 as amended, it cannot be considered an anticipatory reference, and the rejection should be withdrawn. These same comments apply to newly added claim 26 and, in particular, claims 27 and 29.

Claims 1-11, 16, 17 and 22-25 have been rejected pursuant to 35 U.S.C. § 102(b) as allegedly being anticipated by *Keo et al.*, U.S. Patent 5,599,433. As that rejection would be applied to the claims as amended, applicant respectfully traverses. *Keo et al.* does not teach analyzing the clinical sample comprising the protein constituents now reflected in claim 1. On that basis alone, the claims of the instant invention are not anticipated, and the rejection should be withdrawn. The same comments apply to newly added claim 26 and, in particular, claim 28.

Claims 1-5, 10-14, 16, 17 and 22-25 stand rejected pursuant to 35 U.S.C. § 103(a) as allegedly being unpatentable over *Grushka et al.* Applicant respectfully traverses. As noted previously, *Grushka et al.* does not teach or suggest the use of the biological buffers now reflected in claim 1. Indeed, the

Examiner has already acknowledged same, as claim 6 was not rejected on this basis. Accordingly, claim 1 as amended cannot be considered obvious. The same is true, of course, for the claims dependent therefrom. Applicant, therefore, respectfully requests withdrawal of the this rejection.

Claim 15 was rejected pursuant to 35 U.S.C. § 103 as allegedly being obvious over *Grushka et al.* further in view of *Ohmura et al.*, U.S. Patent 5,521,287. However, *Ohmura et al.* does not cure the deficiency previously identified in the application of *Grushka et al.* to claim 1 as amended. Accordingly, applicant respectfully requests withdrawal of this rejection as well.

Claims 1-14, 16, 17 and 22-25 were rejected pursuant to 35 U.S.C. § 103 as allegedly being unpatentable over *Lauer et al.* in view of *Alter et al.*, U.S. Patent 5,753,094. As the rejection would be applied to the claims as amended, applicant respectfully traverses. First, applicant questions whether or not the Patent Office has provided adequate citation to where in the references, or the general skill in the art, one of ordinary skill in the art would look to combine *Lauer et al.* with *Alter et al.* Indeed, from the discussion of the references contained on page 7 of the Official Action mailed June 14, 2004, one has reason to question whether or not these references are combinable.

Lauer et al. nowhere suggests that CZE can be used for analyzing clinical samples, or for the separation of clinical samples containing serum proteins such as albumin and globulin with a CAPS buffer in the presence of KCl. *Alter et al.*, on the other hand, teaches the use of a borate storage buffer or diluent buffer. Indeed, it is entitled "borate storage buffer" There is no teaching, suggestion or motivation to replace the borate buffer in *Alter et al.* with a CAPS buffer, nor is there any teaching or suggestion of record that proper

separation of protein substituents such as albumin and globulin could be effectuated in anything other than after storing with a borate storage buffer.

The present rejection amounts to nothing more than a hindsight reconstruction of applicant's invention. The Patent Office has found the various elements of the claimed invention and discrete references and opined that, because they all relate to the same separation field, they are completely interchangeable. However, hindsight is not a substitute for a teaching, suggestion or motivation to combine these disparate teachings.

Moreover, the buffers of *Alter et al.* are storage buffers, which are adjusted to a pH of between 6 and 8. These are very different than the buffers described in the present invention with enhanced ionic strength, which are used as running buffers, and even those described in *Lauer et al.* Accordingly, applicant respectfully submits that the claims in question are not rendered obvious over the combination of these references, and the rejection should be withdrawn.

The combination in the aforementioned references with *Ohmura et al.* does nothing to overcome these deficiencies, and therefore, applicant respectfully submits that claim 15 is not obvious, and the rejection should be withdrawn. These same comments apply equally to newly added claims 26-29, which reflect specific biological buffers and clinical samples not disclosed in the art.

Finally, a provisional double patenting rejection has been issued against claims 1-33 of co-pending U.S. Patent Application No. 10/052,931. Applicant acknowledges same, but, as this is a provisional rejection, applicant need not comment on same.


Should the Examiner have any questions with regard to the foregoing, he should contact the undersigned, at the

Examiner's convenience, at (908) 654-5000. Should any fee be due and owing in connection with this matter in addition to the extension of time and the appropriate fee submitted herewith, the Examiner is authorized to charge Deposit Account No. 12-1095.

From the foregoing, further and favorable action in the form of a notice of allowance is believed to be next in order, and such action is earnestly solicited.

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Respectfully submitted,

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